

Application No. 10/802,906
Amendment dated November 30, 2007
Reply to Office Action of July 30, 2007

REMARKS

Applicant amended independent claim 7 and dependent claims 38 and 39 and added new claims 42-51 to further define Applicant's claimed invention. Support for the amendment to independent claim 7 and for new claims 42-51 can be found in the specification at least on page 30, lines 20-31 and FIGS. 31A-31D and 33 of the application. No new matter has been added.

I. 35 U.S.C. § 112 Rejection

In the Office Action, the Examiner rejected claims 38 and 39 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant amended claim 38 to recite that the "substantial portion of said bone-contacting surface that is convex in a direction parallel to the length is curved across the width of said body." Applicant amended claim 39 to recite that the "substantial portion of said bone-contacting surface that is convex in a direction parallel to the length is at least in part flat across the width of said body." Applicant submits that the 35 U.S.C. § 112 rejection has been overcome.

II. 35 U.S.C. §§ 102 and 103 Rejections

The Examiner rejected claims 7-10, 13-16, 18-29, 35 and 37-41 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 2,825,329 to Caesar ("Caesar"); rejected claims 30-34 and 36 under 35 U.S.C. § 103(a) as being unpatentable over Caesar; rejected claims 7-29, 35 and 37-41 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,488,543 to Tornier ("Tornier"); and rejected claims 30-34 and 36 under 35 U.S.C. § 103(a) as being unpatentable over Tornier. Applicant respectfully traverses the rejections.

Independent claim 7 recites an implant having a bone contacting surface "configured to be placed against the at least one non-vertebral bone, a substantial portion of said bone-contacting surface being one of (i) convex in a direction parallel to the length of said body and (ii) flat in a direction parallel to the length and across the width of said body." Caesar does not disclose or suggest such structure. Fig. 3 of Caesar shows that the bone-contacting surface of plate 150 is concave across the width (i.e., transverse to the length) of the plate to conform to the shape of the bone on which the plate is placed. Caesar does not disclose a bone contacting surface that is convex in a direction parallel to

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the length of the plate. Nor does Caesar disclose a bone contacting surface that is flat in a direction parallel to the length and across the width of the plate.

The Examiner states that the convex surface of plate 150 of Caesar is the surface that is "opposite of the bone," i.e., that is not bone-contacting. (Office Action, page 3, line 7). Applicant submits that the surface "opposite of the bone" in Caesar is not convex in a direction parallel to the length of the plate, instead it is flat. (See Caesar, FIG. 1).

Applicant respectfully disagrees with the Examiner's contention that plate 150 is "inherently capable of being flipped upside down as a matter of design choice." (Office Action, page 3, lines 7-8). If plate 150 were to be flipped upside down as proposed by the Examiner, the surface to be placed in contact with the bone would not be convex in a direction parallel to length of the plate.

Independent claim 7 recites a locking element "being coupled to said implant prior to the insertion of the bone screws into the bone screw receiving holes." Applicant respectfully disagrees with the Examiner's assertion that plate 140 of Caesar is "a locking element capable of locking the screws." (Office Action, page 3, lines 10-11). Caesar teaches that "when the pins 152 are entered in the openings 70a and the plate 150 pressed into place, these pins 152 pass through the openings 144 in the plate 140," and "the ends of pins 152 indicated at 153 just project from the opposite side of the bone." (Caesar, col. 3, lines 2-6) (emphasis added). Caesar further teaches that "the turned down ends 160" of screws 158 "enter the threaded openings 146 of the plate," and that as each screw advances, "the screw threads will enter the threads in opening 146" of the plate 140. (Caesar, col. 3, lines 12-14, 16-17). Thus, plate 140 in Caesar is coupled to plate 150 as a result of the insertion of bone screws 158 into bone screw receiving holes 146. Caesar does not teach or suggest a locking element being coupled to the implant prior to the insertion of the bone screws as recited in independent claim 7.

Further, Applicant respectfully disagrees with the Examiner's contention that plate 140 can "merely cover the top of plate (150) and be rotated, slid, etc into and out of alignment for allowing the screws through holes (156)." (Office Action, page 3, lines 12-13). In Caesar, pins 142 of plate 140 are moved into holes 66a of slot 94a formed in

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the bone itself. (See Caesar, col. 2, lines 45-51; FIG. 1). Caesar does not teach positioning plate 140 over the top of plate 150.

Applicant respectfully submits that the modification proposed by the Examiner is based not on knowledge available to one of ordinary skill in the art, but on knowledge gleaned only from Applicant's disclosure, thus amounting to impermissible hindsight. (See MPEP § 2143.01 (X) (A)). Applicant also submits that if plate 140 of Caesar covered the top of plate 150, then: (1) the flat shape of plate 140 would not correspond to the curved shape of plate 150; and (2) plate 140 would not secure plate 150 to the bone, rendering the Caesar plate unworkable for its intended purpose.

Independent claim 7, as amended, recites a locking element "movable without deformation from an initial position that permits the insertion of at least one bone screw into said bone screw receiving holes to a final position that retains at least two bone screws to said implant." Caesar does not disclose or suggest such structure. Caesar teaches that after the threads of screws 158 enter the threads in openings 146 of plate 140, "the screw can be driven home without any relative motion taking place between the plates 150 and 140." (Caesar, col. 3, lines 16-19). Caesar also discloses that after the insertion of the screws, the screws "prevent shifting of the plate 140." (Caesar, col. 3, lines 44-46). In Caesar, plate 140 remains in the same position prior to and after the insertion of the screws 158.

Similarly, Tornier does not disclose or suggest the structure of the locking element as recited in independent claim 7. Tornier teaches that disk 11 has "a diameter which partially covers each of heads 3a of screws 3" and that disk 11 "is elastic thereby making possible the passage of heads 3a of screws 3 and the backward movements of the screws 3, in the event that they come in contact with the cortical of the femoral head." (Tornier, col. 2, lines 37-39, 44-48). FIGS. 2 and 3 of Tornier show that elastic disk 11 would be deformed as a result of the backward movement of screw heads 3a out of bone screw receiving holes 6. (Tornier, col. 4, lines 4-7).

Applicant submits that Caesar and Tornier, whether taken alone or when properly combined, do not disclose or suggest all the elements of independent claim 7. Applicant submits that independent claim 7 is patentable over the art cited by the Examiner and that claims 8-41 are allowable at least because these claims depend from an allowable

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Independent claim, or claims dependent therefrom. Applicant submits that the Examiner's rejections of the claims under 35 U.S.C. §§ 102(b) and 103(a) have been overcome.

Newly added independent claim 42 recites an implant with a body, at least two bone screw receiving holes, and a "non-elastic locking element being coupled to said implant prior to the insertion of the bone screws into the bone screw receiving holes."

Newly added independent claim 47 recites an implant with a body, at least two bone screw receiving holes, and a locking element for locking at least two bone screws, "at least a portion of said locking element being adapted to cover at least a portion of at least one of said bone screw receiving holes and being rigid." Applicant submits that Caesar and Tomier, whether alone, or when properly combined, do not disclose or suggest all of the recitations of new independent claims 42 and 47 or claims dependent therefrom.

III. Double Patenting Rejections

The Examiner rejected claims 7-41 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-173 of U.S. Patent No. 6,193,721; claims 1-39 of U.S. Patent No. 6,936,051; and claims 1-117 of U.S. Patent No. 6,398,783 in view of U.S. Patent No. 5,468,242 to Reisberg ("Reisberg"); and provisionally rejected claims 7-41 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-72 of co-pending U.S. Application No. 10/926,734 and claims 1-62 of co-pending Application No. 11/128,556 in view of Reisberg.

Applicant hereby acknowledges the Examiner's provisional obviousness-type double patenting rejections over co-pending Application Nos. 10/926,734, and 11/128,556. Applicant reserves the right to revisit these rejections upon allowance of these applications to determine if a Terminal Disclaimer is required at that time.

Applicant respectfully traverses the Examiner's double patenting rejections as to U.S. Patent Nos. 6,936,051 ("051 patent"), 6,193,721 ("721 patent"), and 6,398,783 ("783 patent") for at least the reasons set forth below.

A. The Combination of the '051, '721 and '783 Patents With Reisberg Does Not Make Applicant's Claimed Invention Obvious

The MPEP states that the "analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. § 103 obviousness

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determination." (See MPEP § 804(II)(B)(1), page 800-21, Rev. 5, Aug. 2006). The Supreme Court recently reaffirmed an objective obviousness analysis in view of the following factual inquiries set forth in *Graham v. John Deere Co.*: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; and (3) resolving the level of ordinary skill in the pertinent art." (See *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007)). As set forth below, Applicant respectfully submits that Applicant's claimed invention is not obvious in view of the '051, '721, or '783 patents in combination with Reisberg.

1. The Scope And Content of the Prior Art

The Examiner's double-patenting rejection identifies the prior art as claims 1-39 of the '051 patent, claims 1-173 of the '721 patent, claims 1-117 of the '783 patent, and Reisberg. The claims of each of the '051, '721, and '783 patents are directed to plates for use in the anterior human cervical spine for contacting at least a portion of at least two cervical vertebral bodies. The claims of the '051 and '783 patents and claims 7, 10, 54, 99, 126, 129, and 132 of the '721 patent, are also directed to anterior cervical plate with a bone-contacting surface that is concave along the longitudinal axis of the plate. Reisberg teaches a "mesh implant for the fixation and immobilization of bone fragments" that could be "contoured to a concave or convex anatomical shape by the surgeon at the time of the operation." (Reisberg, col. 1, lines 6-11 and 34-36).

2. Differences Between the Prior Art and the Claimed Invention

Independent claim 7 recites "an orthopedic implant for engaging at least one non-vertebral bone of the human body." Conversely, the claims of each of the '051, '721, and '783 patents recite plates for use in the anterior human cervical spine for contacting at least a portion of vertebral bodies. Independent claim 7, as amended, recites an implant with a body including a substantial portion of said bone-contacting surface "being one of: (i) convex in a direction parallel to the length of said body and (ii) flat in a direction parallel to the length and across the width of said body." Conversely, the claims of the '051 and '783 patents and claims 7, 10, 54, 99, 126, 129, and 132 of the '721 patent recite a plate with a bone-contacting surface that is concave along the longitudinal axis of the plate.

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Reisberg does not disclose or suggest anterior cervical plates and does not disclose or suggest an implant as recited in independent claim 7.

Applicant submits that it would not be obvious to one of ordinary skill in the art to modify the plates claimed in the '051, '721, and '783 patents such that a substantial portion of said bone-contacting surface is one of: "(i) convex in a direction parallel to the length of said body and (ii) flat along in a direction parallel to the length and across the width of said body" as recited in Applicant's independent claim 7. The '051, '721, and '783 patents each disclose that the "concave curvature [of the plate] in the longitudinal plane conforms to the proper shape of the anterior aspect of the spine with the vertebrae aligned in appropriate lordosis." ('051 patent, col. 13, lines 17-25; '721 patent, col. 13, lines 30-38; '783 patent, col. 13, lines 15-23). Modifying the concave bone-contacting surface of the plates claimed in the '051 and '783 patents and claims 7, 10, 54, 99, 126, 129, and 132 of the '721 patent to be convex would prevent the plates from conforming to the shape of the anterior aspect of the cervical spine. Accordingly, one of ordinary skill in the art would not be motivated to combine the inventions claimed in the '051 and '783 patents or in claims 7, 10, 54, 99, 126, 129, and 132 of the '721 patent with the teachings of Reisberg to form the plate as recited in Applicant's independent claim 7.

Applicant further submits that one of ordinary skill in the pertinent art would not have a reasonable expectation of success when combining the teachings of Reisberg to modify the inventions claimed in the '051 and '783 patents and in claims 7, 10, 54, 99, 126, 129, and 132 of the '721 patent. The concave bone-contacting surfaces along the longitudinal axes of the plates recited in the '051, '721, and '783 patents allow the plates to conform to the natural shape of the anterior aspect of the cervical spine. Assuming, *arguendo*, that these plates were capable of being contoured so as to form a convex bone-contacting surface as taught in Reisberg, one of ordinary skill in the art could not have a reasonable expectation of success applying a plate with bone-contacting surface that is either convex in a direction parallel to the length of the plate or flat in a direction parallel to the length and across the width of the plate to the convex-shaped anterior cervical spine. Such a plate would not work for the purpose intended in the '051, '721, and '783 patents.

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Applicant submits that the factors of a 35 U.S.C. § 103(a) test under *Graham v. John Deere* favor a determination that the implant recited in claims 7-41 of the present application is non-obvious in view of the implants recited in any of the '051, '721, and '783 patents in combination with Reisberg. Accordingly, the double patenting rejection over the '051, '721, and '783 patents in view of Reisberg is improper and should be withdrawn.

B. The Claims of the '051, '721, and '783 Patents are Patentably Distinct From Applicant's Claimed Invention

According to the MPEP, "[t]he general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not the second, while a second claim recites limitations disclosed only for the second species but not the first." (MPEP § 806.04 (b)). Independent claim 7 recites "an orthopedic implant for engaging at least one non-vertebral bone of the human body" and a substantial portion of bone-contacting surface being one of "(i) convex in a direction parallel to the length of said body and (ii) flat in a direction parallel to the length and across the width of said body." These recitations of claim 7 exclude the recitations of claims in the '051, '721, and '783 patents that are directed to inventions for application in the "anterior cervical spine." Modifying the plates claimed in the '051, '721, and '783 patents to have a bone contacting surface that is convex in a direction parallel to the length of the plate or flat in a direction parallel to the length and across the width of the plate would make these plates unsatisfactory for their intended purpose.

The bone-contacting surface being one of convex in a direction parallel to the length of said body and flat in a direction parallel to the length and across the width of said body as recited in claim 7 of the present application is a feature that is exclusive to areas outside of the anterior cervical spine due to the convex curvature of the anterior cervical spine. Conversely, all of the independent claims in the '051, '721, and '783 patents are directed to inventions for application in the "anterior human cervical spine."

Independent claim 1 of the '051 patent recites a lock having an elongated segment having a width, a length longer than said width, the "lock being adapted to retain at least two bone screws to said plate when said length of said elongated segment is generally

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transverse to the longitudinal axis of said plate." Independent claim 1 of the '721 patent recites "a recess associated with said at least first and second of said bone screw receiving holes, said recess having a configuration for retaining a locking element," the "central longitudinal axis of said recess being offset from a transverse line passing through the central longitudinal axis of said first and second bone screw receiving holes." Applicant's independent claim 7 does not recite the above-identified recitations.

Applicant submits that independent claim 7 is directed to a patentably different invention as compared with the claimed inventions recited in the '051, '721, and '783 patents.

C. The Claims of the '051, '721, and '783 Patents are Not a Species of Applicant's Claim 7

Applicant respectfully disagrees with the Examiner's assertion that the claimed inventions in the '051, '721, and '783 patents "define a 'species' of the 'generic' invention of claim 7." (Office Action, page 7). As set forth above, Applicant's independent claim 7 is directed to "an orthopedic implant for engaging at least one non-vertebral bone of the human body" and having a bone-contacting surface "configured to be placed against the at least one non-vertebral bone." All the independent claims in the '051, '721, and '783 patents recite application of plates to the "anterior cervical spine." Applicant submits that the claims of the present application are directed to different anatomical structures and represent a distinct species as compared with the claims of the '051, '721, and '783 patents. Applicant submits that the claims of the present application are not generic to the claims of the '051, '721, and '783 patents, and are therefore not "anticipated" by the "species" of the '051, '721, and '783 patents.

Moreover, Applicant submits that independent claim 7 of the present application cannot be a genus claim to independent claims 1 and 28 of the '721 patent as contended by the Examiner. Claims 1 and 28 of the '721 patent recite that the lower surface of the plate contacts "the cervical vertebral bodies" and do not limit the lower surface to being convex in a direction parallel to the length of the plate or flat in a direction parallel to the length and across the width of the plate. Therefore, the scope of independent claim 7 does not encompass claims 1 and 28 of the '721 patent.

Applicant submits that the double patenting rejections have been overcome.

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CENTRAL FAX CENTER**NOV 30 2007**Application No. 10/802,906
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In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: November 30, 2007By: 

Arriedeo F. Ferraro

Registration No. 37,129

1557 Lake O'Pines Street, NE
Hartville, Ohio 44632
Telephone: (310) 286-9800
Facsimile: (310) 286-2795